

REMARKS

Claim 7 is amended without disclaimer or prejudice, as explained in further detail below. Claims 1-19, 21, 22, 24-28, and 30-34 will be pending in the application upon entry of the present amendment.

The Rejections Under 35 USC § 112 Should be Withdrawn

Claims 1 and 15 are rejected under 35 U.S.C. §112, second paragraph. Citing MPEP §2172.01, the Office action indicates that the claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. With respect to this omitted step, the Office Action indicates that the claims “are incomplete because they lack a correlating step to accomplish the preamble of the claim”.

This rejection is respectfully traversed. With respect to 35 U.S.C. §112, second paragraph, MPEP 2172.01 indicates that:

a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention... (“[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result”...(A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes. *Emphasis added.*

The claims under consideration are processes directed to “A process for analyzing proteins or viruses in a sample comprising:”, as indicated in the preamble of the claims. Claim 1 clearly recites “dividing...into a plurality of aliquots”; “applying...to a first separation step to yield plurality of partially resolved eluates”; and “subjecting...to a second separation step to yield a plurality of resolved fractions” as set forth in detail in the claim. Claim 15 clearly recites “applying...to a first separation step to yield plurality of partially resolved eluates”; and “subjecting...to a second separation step to yield a plurality of resolved fractions”; “digesting said plurality of partially resolved eluates to yield a plurality of digested eluates...” ; and “subjecting said plurality of digested eluates ...to a second separation step to yield a plurality of resolved peptide fractions”; as set forth in detail in the claim. Therefore, the claims distinctly point out and claim the invention as a series of steps as recited in the claims under consideration. Applicant is not aware of a requirement under 35 U.S.C. §112, second paragraph, that a correlating step to accomplish the

preamble must be included as a positive recitation in the claim. Furthermore, Applicants submit that claims 1 and 15, as claimed, are consistent with the guidance provided in MPEP 2172.01 with respect to 35 U.S.C. §112, second paragraph.

In light of the above, Applicants submit the Office Action fails to establish a *prima facie* case of indefiniteness under 35 U.S.C. §112, second paragraph, as applied to claims 1 and 15. Accordingly, Applicants respectfully request that this rejection of the claims under consideration be withdrawn.

Claim 7 is rejected under 35 U.S.C. §112, second paragraph; the Office Action indicating lack of antecedent basis for recitation of “mass spectrometry”. Claim 7 is amended as set forth above to explicitly include the recitation. Therefore, this rejection is obviated. Support for the amendment is found throughout the specification and the claims as originally filed.

In light of all of the above, Applicants respectfully request that this rejection of claims 1, 15, and 7 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Rejections Under 35 USC § 102 Should be Withdrawn

Claims 1-6, and 8-11, are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (Anal. Chem. (2002) 74: 809-820). This rejection is respectfully traversed.

Included in the basis for this rejection, the Office Action indicates: “Wagner teaches a process for analyzing proteins in a sample comprising dividing a sample into plurality of aliquots (page 810, right column, 5th and 6th full paragraph); applying to a first separation step to yield a plurality of partially resolved eluates...”.

Independent claim 1 contains the recitation, “...applying said plurality of aliquots in parallel to a first separation step...”, *emphasis added*. Applicants respectfully submit that, at a minimum, the Office Action has not established that the Wagner et al. reference teaches the limitation, “...in parallel...” with respect to the first separation step as claimed in claim 1 under consideration.

As such, Applicants submit that the Office Action has failed to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b), as applied to claims 1-6, and 8-11. Accordingly, Applicants respectfully request that this rejection of the claims under consideration be withdrawn.

The Rejections Under 35 USC § 103(a) Should be Withdrawn

Claims 1-12, 14-19, 21, 22, 24-25, 27-28, 30-32, 34 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Wagner et al. in view of Gygi et al. (PNAS 2000 97(17):9390-9395) and Kachman et al. (Anal. Chem. 2002 74:1779-1791). This rejection is respectfully traversed.

Consistent with the bridging sentence of Office Action pages 2-3, where the recitation of “in parallel” is not included with respect to a first separation step, Applicant submits that at a minimum, the primary reference of Wagner et al. is deficient with respect to teaching the limitations of “...applying said plurality of aliquots in parallel to a first separation step...”, *emphasis added*. In contrast, independent claims 1 and 15 clearly include the recitation, “...applying said plurality of aliquots in parallel to a first separation step...”.

This deficiency of the primary reference is not removed in view of the Gygi et al., and the Kachman et al. references, alone or in combination. The Office Action merely alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wagner by digesting and tagging protein samples in each fraction to analyze protein with MALDI mass spectrometer because Wagner teaches that multidimensional separation can be performed on digested protein (page 810, right column, 1st full paragraph) and Gygi teaches a digestion step in the mass spectrometer protein analysis. The Office Action further alleges that one would have been motivated to make the modification and automate the process using a robotic equipment because Wagner et al. specifically described the benefits of on-line array fractionation onto targets for MALDI-TOFMS (page 820, right column, 1st full paragraph), and would reasonably have expected success in view of Kachman’s teaching of a protein tagging method for accurate mass analysis (page 1786, left column, lines 16-18) and its potential for automation. Thus, the Office Action does not address the deficiency of the primary reference. Nor does it provide any reasoning as to how this deficiency is removed in view of Gygi et al. (PNAS 2000 97(17):9390-9395) and/or Kachman et al. (Anal. Chem. 2002 74:1779-1791).

Therefore, Applicants submit that the Office Action has failed to establish a *prima facie* case under 35 U.S.C. §103(a) with respect to the claims under consideration. In light of the above, Applicants respectfully request that this rejection of the claims under consideration be withdrawn.

Claims 1-6, 8-11, 13, 26, 33 were rejected under 36 U.S.C. 103(a) as being unpatentable over the combination of Wagner et al. in view of Miliotis et al. (J. Chromatography A 2000;886:99-110).

As stated above, the primary reference of Wagner et al. is deficient with respect to teaching the limitations of the “...applying said plurality of aliquots in parallel to a first separation step...”, *emphasis added*. In contrast, independent claims 1 and 15 clearly include the recitation, “...applying said plurality of aliquots in parallel to a first separation step...”.

This deficiency of the primary reference is not removed in view of the Miliotis et al. reference. The Office Action merely alleges obviousness of affixing a machine-readable label to the fraction/eluates collection to simplify automation and increase the robustness of the system. See Office Action, page 5,

paragraph 5. Thus, the Office Action does not address the deficiency of the primary reference. Nor does it provide any reasoning as to how this deficiency is removed in view of Miliotis et al.

Therefore, in light of all of the above, Applicants submit that the Office Action has failed to establish a *prima facie* case under 35 U.S.C. §103(a) with respect to the claims under consideration. Accordingly, Applicants respectfully request that this rejection of the claims under consideration be withdrawn.

In view of the above amendments and remarks, applicants believe the pending application is in condition for allowance, and such allowance is respectfully solicited.

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Respectfully submitted,

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